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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,315	01/09/2001	Jeremy Carver	12243.15USWO	8757

23552 7590 03/12/2002

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EXAMINER
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GARCIA, MAURIE E

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 03/12/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/701,315

Applicant(s)

Carver et al

Examiner

Maurie E. Garcia, Ph. D.

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-17 is/are pending in the application

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-17 are subject to restriction and/or election requirements

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

### DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

#### *Election/Restriction*

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
2. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention from the following groups to which the claims must be restricted.
  - I. Claims 1-6, drawn to a combinatorial library.
  - II. Claims 7-9 (in part), drawn to a nucleoside peptide molecule where X= H.
  - III. Claims 7-9 (in part), 10 and 11, drawn to a nucleoside peptide molecule where X= -COOH.
  - IV. Claims 7-9 (in part) and 12, drawn to a nucleoside peptide molecule where X= -OSO<sub>3</sub>H or -(CH<sub>2</sub>)<sub>q</sub>SO<sub>3</sub>H.
  - V. Claim 13 drawn to a process for preparing a combinatorial library.
  - VI. Claim 14 drawn to a method of using a combinatorial library.

- VII. Claim 15 drawn to a solid phase bioassay.
- VIII. Claim 16 drawn to a method for identifying a compound.
- IX. Claim 17 drawn to a pharmaceutical composition.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.

4. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art".

5. First, there does not appear to be a technical feature that links the claims of Groups VII and VIII to the rest of the claims as there is nothing in claims 15 or 16 that requires the use of any of the compounds or libraries set forth in the remainder of the claims. However, if the "test compound" in these claims is deemed to be the same as the compound claimed in claim 7, then the following applies (see next paragraph).

6. The technical feature that links all of the claims is the nucleoside peptide molecule comprising a nucleoside monomer, spacer monomer and cap monomer (see

instant claims 7 & 8). The groups lack unity because the claimed molecules (and libraries thereof) are known in the art as disclosed by Lee et al. This reference is described below.

7. Lee et al disclose compounds that read on those claimed in instant claims 7 & 8; see compounds **30** and **31** on page 8691 of the reference. The compounds of Lee have a nucleoside monomer, spacer monomer and cap monomer, where the spacer monomer comprises an “amide linked amino acid residue” (as defined by applicant’s claims). Referring to the structure in instant claim 8, the compounds of Lee have Z and Z’ = OH, X = H, R is –NHCO- with the rest of the molecule serving as the “cap monomer”. As two compounds are disclosed, a library is anticipated. Also, Lee et al specifically refer to making libraries in the last paragraph on page 8691 of the reference.

8. Moreover, the products of Groups I-IV and IX are different in structure and their modes of action and chemical reactivity would be different. Further, they represent separate and distinct products (different inventive concepts). They differ in respect to their properties, the synthetic methodology for making them and/or their use. The methods of Groups V-VIII also represent different inventive concepts as they represent different methods, with different steps, different reagents and/or different end results.

9. Also see MPEP 1850: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the

dependent claims. By dependent claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression category of claim referring to the classification of claims according to the subject matter of the invention claimed, for example, product, process, use or apparatus or means, etc.).

10. Finally, see 37 CFR § 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage, cited in part below (especially sections (c) and (d)).

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- A product and a process specially adapted for the manufacture of said product;  
or
- A product and process of use of said product; or
- A product, a process specially adapted for the manufacture of the said product,  
and a use of the said product; or
- A process and an apparatus or means specifically designed for carrying out the  
said process; or
- A product, a process specially adapted for the manufacture of the said product,  
and an apparatus or means specifically designed for carrying out the  
said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

11. The instant 371 application contains multiple products and methods, where the feature that links the claims is known in the art, as set forth above. Thus, the instant claims lack unity of invention.

12. This application contains claims directed to more than one species of the generic invention for Groups II, III and IV. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 (see paragraphs 14-16 below).

13. If applicant elects the invention of any of Groups II, III or IV, applicant is required to elect from the following patentably distinct species. Claims 7 and 8 are generic to each group.

Species of molecule

A *specific* nucleoside peptide molecule should be elected, for purposes of search, showing the nucleoside monomer, spacer monomer and cap monomer and all bonds between them.

14. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

15. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art". For example, unity of invention is fulfilled if:

- (a) all alternatives have a common property; **and**
- (b) (i) a common structure is present, i. e. a significant structural element is shared by all alternatives, or
- (b) (ii) in cases where the common structure can not be the unifying criterion, all alternatives belong to a recognized class of compounds in the art to which the invention pertains. (MPEP 1850).

16. In the instant case, part (a) above is not fulfilled because all claimed species of molecule do not have a common property (i.e. they bind differently to receptors). Further, all of the species do not belong to a recognized class of compounds in the art to which they pertain (i.e. the molecules can have widely varying structures). Moreover, the claimed molecules are known in the art, see paragraphs 6-7 above.

For these reasons, election under these rules is proper and required.



17. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

19. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.  
March 7, 2002



MAURIE E. GARCIA, PH.D.  
PATENT EXAMINER